

AABB's Comprehensive List of Regulatory Resources for Platelets 06/30/21

- AABB Association Bulletin #21-02 Considerations for Implementation of FDA Guidance on Bacterial Risk Controls for Platelets
- AABB Bacterial Risk Reference Sheets
- Flowchart: Provides overview of <u>Timelines for Testing Strategies for Apheresis Platelets</u>
- <u>Toolkit for Transfusion Services: FDA Registration Requirements when Extending Platelet</u> <u>Expiration to Day-6 or Day-7</u>
- Platelet Codes <u>List of common platelet codes</u> you may use to <u>proactively update your</u> <u>computer system</u>:
 - It is possible that you will receive unexpected platelet codes as platelet products are imported by your supplier and shipped to your transfusion service.
 - Blood suppliers and transfusion services may use this list to prepare.
 - <u>We appreciate the efforts of multiple blood suppliers</u> who have supported patient care by sharing the codes they are most likely to use in the coming months.
- <u>Checklist for Biologics License Application (BLA) for Platelets Leukocytes Reduced Collected by</u> <u>Apheresis</u>
- All Regulatory Resources for 2021
- <u>All Regulatory Resources for 2019-2020</u>
- FDA links:
 - <u>Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion</u> <u>Services to Enhance the Safety and Availability of Platelets for Transfusion; Guidance for</u> <u>Industry</u> (Updated December 17, 2020) - 12/2020
 - o FDA's Blood Establishment Registration and Product Listing
 - o FDA's Blood Establishment Registration and Product Listing On-Line Contact Form